

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

CEPHALON, INC. and)
CIMA LABS, INC.,)
)
Plaintiffs,)
)
v.) C.A. No. 10-00123-SLR
)
SANDOZ INC.,)
)
Defendant.)
)

SANDOZ INC.'S ANSWER, DEFENSES, AND COUNTERCLAIMS

Defendant Sandoz Inc. (hereinafter "Sandoz") hereby answers the Complaint of Plaintiffs Cephalon, Inc. and CIMA LABS INC. (hereinafter collectively, "Plaintiffs"), as follows:

THE PARTIES

1. Sandoz lacks knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 1, and therefore denies these allegations.
2. Sandoz lacks knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 2, and therefore denies these allegations.
3. Admitted.
4. Sandoz admits that it manufactures and sells generic drugs throughout the United States, including Delaware. Sandoz denies the remaining allegations in Paragraph 4.

JURISDICTION AND VENUE

5. Sandoz admits that this purports to be an action for patent infringement of U.S. Patents Nos. 6,200,604 B1 (“the ‘604 patent”) and 6,974,590 B2 (“the ‘590 patent”) under the Patent Laws of the United States. Sandoz admits that copies of the ‘604 and ‘590 patents are attached to the Complaint. Sandoz denies the remaining allegations in Paragraph 5.

6. Sandoz does not contest subject matter jurisdiction in this Court for the purposes of this action only. Sandoz denies the remaining allegations in Paragraph 6.

7. Sandoz does not contest personal jurisdiction in this Court for the purposes of this action only. Sandoz denies the remaining allegations in Paragraph 7.

8. Sandoz does not contest personal jurisdiction in this Court for the purposes of this action only. Sandoz denies the remaining allegations in Paragraph 8.

9. Sandoz does not contest personal jurisdiction in this Court for the purposes of this case. Sandoz denies the remaining allegations in Paragraph 9.

10. Admitted.

11. Admitted.

12. Sandoz admits that it has derived revenue from sales of pharmaceutical products in Delaware. However, such sales were not for the pharmaceutical products at issue in this case. Sandoz denies the remaining allegations in Paragraph 12.

13. Sandoz admits that it has made purchases from Agilent and LabWare.

However, such purchases were not related to the pharmaceutical products at issue in this case.

Sandoz denies the remaining allegations in Paragraph 13.

14. Sandoz admits that it has previously availed itself of this forum for purposes of litigating defenses and counterclaims in patent disputes brought against Sandoz. However, such patent disputes were not related to the pharmaceutical products at issue in this case. Sandoz denies the remaining allegations in Paragraph 14.

15. Sandoz admits that it consented to personal jurisdiction in *Daiichi Sankyo Co., Ltd. v. Sandoz Inc.*, C.A. No. 09-898 (D. Del.) for the purpose of that case. However, the *Daiichi* case is not related to the pharmaceutical products at issue in this case. Sandoz denies the remaining allegations in Paragraph 15.

16. Sandoz admits that it has previously engaged the services of law firms located in Delaware, and Sandoz has previously defended patent cases brought against it in this jurisdiction. However, such prior engagements and cases were not related to the pharmaceutical products in this case. Sandoz denies the remaining allegations in Paragraph 16.

17. Sandoz does not contest venue for the purposes of this action. Sandoz denies the remaining allegations in Paragraph 17.

THE PATENTS IN SUIT

18. Sandoz admits that on March 13, 2001, the '604 patent titled "Sublingual Buccal Effervescent" was issued by the United States Patent and Trademark Office ("PTO"). Sandoz denies the remaining allegations in Paragraph 18.

19. Sandoz admits that on December 13, 2005, the ‘590 patent titled “Sublingual Buccal Effervescent” was issued by the PTO. Sandoz denies the remaining allegations in Paragraph 19.

20. Sandoz admits that the FDA’s electronic Orange Book lists “Cephalon” as the holder of an approved New Drug Application (“NDA”) No. 21-947 for FENTORA® buccal tablets in doses of 0.1, 0.2, 0.3, 0.4, 0.6 and 0.8 mg. The FDA’s electronic Orange Book lists the ‘604 and ‘590 patents in the Patent Exclusivity Search Results for NDA No. 21-947. Sandoz denies the remaining allegations in Paragraph 20.

**ACTS GIVING RISE TO THIS ACTION FOR
INFRINGEMENT OF THE ‘604 AND ‘590 PATENTS**

21. Sandoz admits that it reviews pharmaceutical patents. Sandoz denies the remaining allegations in Paragraph 21.

22. Sandoz admits that it reviewed the patents-in-suit and information relating to FENTORA®. Sandoz admits that it decided to file an Abbreviated New Drug Application (“ANDA”) seeking to market fentanyl citrate tablets.

23. Sandoz admits that it submitted ANDA No. 200-676 to the FDA under 21 U.S.C. §355(j). ANDA No. 200-676 seeks FDA approval for the commercial manufacture, use, offer for sale, and/or sale of fentanyl citrate buccal tablets containing 0.1, 0.2, 0.3, 0.4, 0.6 and 0.8 mg of fenanyl citrate (the “Sandoz Generic Products”) in the U.S. before the expiration of the ‘604 and ‘590 patents. Sandoz denies the remaining allegations in Paragraph 23.

24. Sandoz admits that as part of its ANDA No. 200-676 Sandoz did file a Paragraph IV Certification pursuant to 21 U.S.C. §355(j)(2)(A)(vii)(IV), alleging that the

claims of the '604 and '590 patents are "invalid, unenforceable, and/or not infringed by the manufacture, use, sale or offer for sale of" the Sandoz Generic Products in the U.S. Sandoz admits that it sent a Paragraph IV letter to Plaintiffs on January 5, 2010, which stated that Sandoz had submitted data to the FDA regarding the "bioavailability and/or bioequivalence" of the Sandoz Generic Products and FENTORA®. Sandoz denies the remaining allegations in Paragraph 24.

25. Sandoz admits that the Paragraph IV letter notified Plaintiffs that its ANDA No. 200-676 included a Paragraph IV Certification stating that the '604 and '590 patents are invalid, unenforceable, and/or not infringed by the Sandoz Generic Products. Sandoz denies the remaining allegations in Paragraph 25.

26. Denied.

27. Sandoz admits that it continues to seek approval of ANDA No. 200-676 from the FDA. Sandoz denies the remaining allegations in Paragraph 27.

COUNT I
Infringement of the '604 Patent Under 35 U.S.C. §271(e)(2)

28. Sandoz incorporates by reference its responses to Paragraphs 1-27.

29. Sandoz admits that it submitted ANDA No. 200-676. Sandoz denies the remaining allegations in Paragraph 29.

30. Denied.

COUNT II
Declaratory Judgment of Infringement of the '604 Patent
Under 35 U.S.C. §271(e)(2)

31. Sandoz incorporates by reference its responses to Paragraphs 1-30.
32. Sandoz admits that Plaintiffs allege a claim under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202. Sandoz denies the remaining allegations in Paragraph 32.
33. Denied.
34. Denied.
35. Denied.
36. Denied.
37. Denied.

COUNT III
Infringement of the '590 Patent Under 35 U.S.C. §271(e)(2)

38. Sandoz incorporates by reference its responses to Paragraphs 1-37.
39. Sandoz admits that it submitted ANDA No. 200-676. Sandoz denies the remaining allegations in Paragraph 39.
40. Denied.

COUNT IV
Declaratory Judgment of Infringement of the '590 Patent
Under 35 U.S.C. §271(e)(2)

41. Sandoz incorporates by reference its responses to Paragraphs 1-40.

42. Sandoz admits that Plaintiffs allege a claim under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202. Sandoz denies the remaining allegations in Paragraph 42.

43. Denied.

44. Denied.

45. Denied.

46. Denied.

47. Denied.

EXCEPTIONAL CASE

48. Denied.

INJUNCTIVE RELIEF

49. Denied.

* * *

Sandoz denies every allegation not expressly admitted herein. Sandoz further denies that Plaintiffs are entitled to the relief requested.

SANDOZ'S AFFIRMATIVE DEFENSES

Sandoz hereby raises the following affirmative defenses to the claims alleged in the Complaint based on knowledge or information known or available at this time, or believed by Sandoz to be true at this time.

First Affirmative Defense
(Failure to State a Claim Upon Which Relief May Be Granted)

The Complaint fails to state a claim upon which relief may be granted.

Second Affirmative Defense
(Non-Infringement of the '604 Patent)

Sandoz has not directly or indirectly infringed any valid claim of the '604 patent, literally or under the doctrine of equivalents, by making, using, selling, offering for sale or importing any product into the United States that is the subject of Sandoz's ANDA No. 200-676, nor do Sandoz's activities relating to the filing of ANDA No. 200-676 result in infringement of any valid claim of the '604 Patent.

Third Affirmative Defense
(Non-Infringement of the '590 Patent)

Sandoz has not directly or indirectly infringed any valid claim of the '590 patent, literally or under the doctrine of equivalents, by making, using, selling, offering for sale or importing any product into the United States that is the subject of Sandoz's ANDA No. 200-676, nor do Sandoz's activities relating to the filing of ANDA No. 200-676 result in infringement of any valid claim of the '590 Patent.

**Fourth Affirmative Defense
(Invalidity of the '604 Patent)**

One or more claims of the '604 patent are invalid for failure to comply with one or more of the statutory provisions of 35 U.S.C. §§ 101, *et seq.*, including §§101, 102, 103 and/or 112.

**Fifth Affirmative Defense
(Invalidity of the '590 Patent)**

One or more claims of the '590 patent are invalid for failure to comply with one or more of the statutory provisions of 35 U.S.C. §§ 101, *et seq.*, including §§101, 102, 103 and/or 112.

**Sixth Affirmative Defense
(Reservation of Additional Defenses)**

Sandoz reserves any other defenses, at law or in equity, that may be available now or may become available in the future based on discovery or any other factual investigation in this action.

COUNTERCLAIMS

As separate and independent Counterclaims against Plaintiffs/Counterclaim-Defendants Cephalon, Inc. and CIMA LABS, INC. (collectively referred to as "Plaintiffs" and/or "Counterclaim-Defendants"), Sandoz Inc. ("Sandoz") hereby alleges as follows:

The Parties

1. Plaintiff/Counterclaim-Defendant Cephalon, Inc. purports to be a Delaware corporation having its principal place of business at 41 Moores Road, Frazer, Pennsylvania. (Complaint, Paragraph 1.)

2. Plaintiff/Counterclaim-Defendant CIMA LABS, INC. purports to be a Delaware corporation having a principal place of business at 7325 Aspen Lane, Brooklyn Park, Minnesota. (Complaint, Paragraph 2.)

3. Sandoz is a corporation organized and existing under the laws of Colorado with its principal place of business at 506 Carnegie Center, Suite 400, Princeton, New Jersey.

Jurisdiction and Venue

4. These Counterclaims arises under the Patent Laws of the United States, 35 U.S.C. § 1 *et seq.*, and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

5. This Court has original jurisdiction over the subject matter of these Counterclaims under 28 U.S.C. §§ 1331 and 1338(a).

6. This Court has personal jurisdiction over Plaintiffs/Counterclaim-Defendants at least because they have availed themselves of the rights and privileges of this forum by suing Sandoz in this District in relation to this action, and because Plaintiffs/Counterclaim-Defendants conduct substantial business in, and have regular and systematic contacts with this District.

7. Venue is proper in this District under 28 U.S.C. §§ 1391(b).

Factual Background

8. U.S. Patent No. 6,200,604 (“the ‘604 patent”) entitled “Sublingual Buccal Effervescent” was issued by the United States Patent and Trademark Office (“PTO”) on March 13, 2001.

9. Plaintiff/Counterclaim-Defendant CIMA LABS, INC. purports to be the owner by assignment of all rights, title and interest in and to the ‘604 patent, including all rights to sue and recover for infringement. (Complaint, Paragraph 18.)

10. U.S. Patent No. 6,974,590 (“the ‘590 patent”) entitled “Sublingual Buccal Effervescent” was issued by the PTO on December 13, 2005.

11. Plaintiff/Counterclaim-Defendant CIMA LABS, INC. purports to be the owner by assignment of all rights, title and interest in and to the ‘590 patent, including all rights to sue and recover for infringement. (Complaint, Paragraph 19.)

12. The FDA electronic Orange Book lists “Cephalon” as the holder of an approved New Drug Application (“NDA”) No. 21-947 for FENTORA® brand fentanyl tablets including 0.1, 0.2, 0.3, 0.4, 0.6 and 0.8 mg of fentanyl citrate, and the Orange Book lists the ‘604 and ‘590 patents for FENTORA®.

13. Sandoz filed ANDA No. 200-676 with the FDA under 21 U.S.C. §355(j) for the approval of fentanyl citrate buccal tablets including 0.1, 0.2, 0.3, 0.4, 0.6 and 0.8 mg of fentanyl citrate (“Sandoz Generic Products”) before the expiration of the ‘604 and ‘590 patents. Sandoz filed a Paragraph IV Certification pursuant to 21 U.S.C. §355(j)(2)(A)(vii)(IV), alleging that the ‘604 and ‘590 patents are “invalid, unenforceable, and/or not infringed by the manufacture, use, sale or offer for sale of” Sandoz’s Generic Products that are the subject of Sandoz’s ANDA No. 200-676.

14. On February 16, 2010, Plaintiffs/Counterclaim-Defendants filed a Complaint against Sandoz in this District alleging infringement of the '604 and '590 patents, including infringement due to the filing of Sandoz's ANDA No. 200-676.

15. As evidenced by Plaintiffs' Complaint and Sandoz's Answer and Defenses thereto, there is an actual, substantial and continuing justiciable case or controversy between the parties regarding infringement of and invalidity of the claims of the patents-in-suit.

COUNT I
(Declaratory Judgment of Non-Infringement of the '604 Patent)

16. Sandoz restates Paragraphs 1-15 of these Counterclaims as if set forth fully herein.

17. Plaintiffs have alleged that Sandoz has infringed the '604 Patent, and Sandoz has denied this allegation.

18. Sandoz's filing of ANDA No. 200-676 and the proposed activities of Sandoz under ANDA No. 200-676 have not, and would not, directly or indirectly infringe any valid claim of the '604 patent, either literally or under the doctrine of equivalents.

19. Sandoz is entitled to a judicial determination that Sandoz's filing of ANDA No. 200-676 does not result in infringement of any valid claim of the '604 patent and the proposed Sandoz Generic Products that are the subject of ANDA No. 200-676 have not, and would not, directly or indirectly infringe any valid claim of the '604 patent if made, used, sold, offered for sale and/or imported into the United States, either literally or under the doctrine of equivalents.

COUNT II
(Declaratory Judgment of Non-Infringement of the '590 Patent)

20. Sandoz restates Paragraphs 1-15 of these Counterclaims as if set forth fully herein.

21. Plaintiffs have alleged that Sandoz has infringed the '590 Patent, and Sandoz has denied this allegation.

22. Sandoz's filing of ANDA No. 200-676 and the proposed activities of Sandoz under ANDA No. 200-676 have not, and would not, directly or indirectly infringe any valid claim of the '590 patent, either literally or under the doctrine of equivalents.

23. Sandoz is entitled to a judicial determination that Sandoz's filing of ANDA No. 200-676 does not result in infringement of any valid claim of the '590 patent and the proposed Sandoz Generic Products that are the subject of ANDA No. 200-676 have not, and would not, directly or indirectly infringe any valid claim of the '590 patent if made, used, sold, offered for sale and/or imported into the United States, either literally or under the doctrine of equivalents.

COUNT III
(Declaratory Judgment of Invalidity of the '604 Patent)

24. Sandoz restates Paragraphs 1-15 of these Counterclaims as if set forth fully herein.

25. One or more of the claims of the '604 Patent are invalid for failure to comply with one or more of the statutory provisions of 35 U.S.C. §§ 101, *et seq.*, including §§101, 102, 103 and/or 112.

26. Sandoz is entitled to a judicial determination that one or more claims of the '604 patent are invalid for failure to comply with the statutory provisions of 35 U.S.C. §§ 101, *et seq.*, including §§101, 102, 103 and/or 112.

COUNT IV
(Declaratory Judgment of Invalidity of the '590 Patent)

27. Sandoz restates Paragraphs 1-15 of these Counterclaims as if set forth fully herein.

28. One or more of the claims of the '590 Patent are invalid for failure to comply with one or more of the statutory provisions of 35 U.S.C. §§ 101, *et seq.*, including §§101, 102, 103 and/or 112.

29. Sandoz is entitled to a judicial determination that one or more claims of the '590 patent are invalid for failure to comply with the statutory provisions of 35 U.S.C. §§ 101, *et seq.*, including §§101, 102, 103 and/or 112.

COUNT V
(Exceptional Case)

30. Plaintiffs Complaint is baseless, and the allegations of infringement therein without merit due to the invalidity of the '604 and/or '590 patents, thereby rendering this an exceptional case under 35 U.S.C. §285.

PRAYER FOR RELIEF

WHEREFORE, Sandoz respectfully prays for judgment as follows:

- (i) Dismissal of Plaintiffs' Complaint with prejudice and entry of judgment in favor of Sandoz;
- (ii) Judgment that the '604 and/or '590 patent claims were not infringed by Sandoz's filing of ANDA No. 200-676 and that the proposed Sandoz Generic Products that are the subject of ANDA No. 200-676 have not, and would not, directly or indirectly infringe any valid claim of the '604 and/or '590 patents if made, used, sold, offered for sale and/or imported into the United States, either literally or under the doctrine of equivalents;
- (iii) Judgment that one or more claims of the '604 and/or '590 patents are invalid under one or more of the statutory provisions of Title 35 of the United States Code;
- (iv) An award to Sandoz of its costs;
- (v) Judgment that this is an exceptional case and an award to Sandoz of its reasonable attorneys' fees and costs under 35 U.S.C. § 285 and/or the inherent discretion of the Court; and
- (vi) Such further relief as this Court may deem just, equitable and appropriate.

Dated: March 22, 2010

YOUNG, CONAWAY, STARGATT & TAYLOR, LLP



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CERTIFICATE OF SERVICE

I, Karen Keller, Esquire, hereby certify that on March 22, 2010, I caused to be electronically filed a true and correct copy of the foregoing document with the Clerk of the Court using CM/ECF, which will send notification that such filing is available for viewing and downloading to the following counsel of record:

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I further certify that on March 22, 2010, I caused a copy of the foregoing document to be served by e-mail on the above-listed counsel of record and on the following in the manner indicated:

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Dated: March 22, 2010

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